APR 3 0 2001

Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760

Section 9
510(K) SUMMARY

K010993

Provided in accordance with 21 CFR 807.92

SPONSOR:	Boston Scientific Corporation (BSC) Microvasive Endoscopy Division One Boston Scientific Place Natick, MA 01760
CONTACT/SUBMITTER:	Lisa Quaglia Regulatory Affairs Manager Tel: 508-650-8267
DATE OF SUBMISSION:	April 2, 2001
DEVICE:	Alien™ RX Micro Cannula
Trade Name: Common Name: Classification:	Alien™ Micro Cannula Cannula Endoscope and Accessories Classified Under 21 CFR Part 876, Section 1500. Classified as a Class II Device.
PREDICATE DEVICE:	Contour™ ERCP Cannula (K833417, ERCP Cannula)
DEVICE DESCRIPTION:	The proposed Alien™ RX Micro Cannula is a single lumen cannula. It is compatible with the Boston Scientific Microvasive Endoscopy's Rapid Exchange™ platform, and is capable of accommodating a .025" guidewire while passing through a .035" lumen.
INTENDED USE:	The Alien™ RX Micro Cannula is intended for use to cannulate and inject contrast media into the biliary and pancreatic ductal systems. Contrast medium is injected through the cannula and fluoroscopy or x-ray is performed to obtain a cholangiogram.
COMPARISON OF CHARACTERISTICS:	The proposed device is substantially equivalent to currently marketed devices used for cannulation and injection of contrast media into the biliary and pancreatic ductal systems.
PERFORMANCE DATA:	The proposed device is substantially equivalent to currently marketed ERCP cannulating devices in terms of performance characteristics tested and biocompatibility.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 3 0 2001

Ms. Lisa M. Quaglia
Regulatory Affairs Manager
Microvasive Endoscopy
Boston Scientific Corporation
One Boston Scientific Place
NATICK MA 01760-1537

Re: K010993
Alien™ RX Micro Cannula, Model 4530
Dated: April 2, 2001
Received: April 3, 2001
Regulatory Class: II
21 CFR §876.1500/Procode: 78 KOG

Dear Ms. Quaglia:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760

Indications for Use Statement

510(k) Number (if known) K010993

Device Name Alien™ RX Micro Cannula

Indications for Use The Alien™ RX Micro Cannula is indicated for use to cannulate and inject contrast media into the biliary and pancreatic ductal systems. Contrast medium is injected through the cannula and fluoroscopy or x-ray is performed to obtain a cholangiogram.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the Counter Use _____
(Per 21 CFR 801.109)

David A. Segura
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K010993